

III. REMARKS/ARGUMENTS

A. Status of the Application

Claims 1, 5, 8 and 10-35 are pending. Claims 23-35 have been withdrawn from consideration. Claims 1, 5, 8, 10-12, 15-16, 18-19 and 21-22 have been amended. Claims 2-4, 6-7 and 9 have been cancelled. Reconsideration of claims 1, 5, 8 and 10-22 in light of the following remarks is respectfully requested.

B. Restriction Requirement

The Office action indicated that restriction was required under 35 U.S.C. §121 to one of the following groups of claims:

Group I Claims 1-22, drawn to an antioxidant composition.

Group II Claims 23-35, drawn to a method of measuring activity of an antioxidant.

Applicants hereby confirm the provisional election, without traverse, of the claims of Group I for prosecution herein.

C. Rejections under 35 USC § 103(a)

Claims 1-14, 18 and 20 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,291,533 to Fleischner ("Fleischner '533"). As noted above, claims 2-4, 6-7 and 9 have been cancelled. Insofar as it may be applied to the present claims, this rejection is respectfully traversed.

Independent claim 1 is directed to an antioxidant composition that includes a flavonoid and a mixture of at least two forms of vitamin E as primary ingredients and bush plum, green tea extract and grape skin extract as secondary ingredients. The primary ingredients are present in the composition in an amount of 30% to 85% by weight and the secondary ingredients are present in the composition in an amount of 15% to 70% by weight. Also, the flavonoid and the mixture of vitamin E forms are present in the composition in a weight ratio of from 40/60 to

90/10 percent. According to claim 1 the flavonoid is selected from the group consisting of a flavone, a flavonol, an isoflavone, an isoflavonol, an analogue thereof, a pharmaceutically acceptable salt thereof, and a mixture thereof. Also according to claim 1, the at least two forms of vitamin E are selected from the group consisting of alpha, beta, delta, epsilon, gamma, zeta, eta, xi1, xi2, and sigma tocopherols, and alpha, beta, delta and gamma tocotrienols, and derivatives thereof. Claims 5, 8, 10-14, 18 and 20 depend from and include at least the same elements as claim 1.

As the PTO recognizes in MPEP §2142:

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.

The Examiner clearly cannot establish a *prima facie* case of obviousness in connection with claim 1 for the following reasons.

35 U.S.C. §103(a) provides that:

[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains ... (emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

Fleischner '533 does not teach, suggest or motivate an antioxidant composition that includes a flavonoid and a mixture of at least two forms of vitamin E as primary ingredients and bush plum, green tea extract and grape skin extract as secondary ingredients in which the primary ingredients are present in the composition in an amount of 30% to 85% by weight and the secondary ingredients are present in the composition in an amount of 15% to 70% by weight, and in which the flavonoid and the mixture of vitamin E forms are present in the composition in a weight ratio of from 40/60 to 90/10 percent, as claimed in claim 1.

Instead, Fleischner '533 discloses various dietary supplement compositions that are said to be designed to be responsive to specific blood types and to be "useful in achieving and maintenance of a healthy status". (Fleischner '533, Abstract and Column 2, lines 33-40). Fleischner '533 discloses a dietary supplement composition that is alleged to be designed for

humans with Type A blood which includes 50-500 mg. of Vitamin C, 25-400 IU of Vitamin E (as d-alpha-tocopheryl succinate and 50% from natural d-alpha-, d-beta-, d-gamma-, and d-delta-tocopherols), 100-400 mcg. of folate, 10-50 mcg. of Vitamin B-12, 25-200 mg. of Hawthorn berry standardized extract, 50-250 mg. of quercetin dihydrate, 50-200 mg. of milk thistle seed extract, 10-50 mg. of alfalfa leaf, 10-50 mg. of Aloe vera leaf gel 200:1 concentrate, 10-100 mg. of Burdock root, 10-50 mg. of Fenugreek seed, 10-100 mg. of ginger root, 50-200 mg. of green tea leaf extract, 25-300 mg. of St. John's Wort standardized extract, 10-50 mg. of slippery elm bark, 10-50 mg. of skull cap root, 10-50 mg. of parsley leaf, 10-100 mg. of dandelion root, 10-50 mg. of chamomile flower, 10-50 mg. of sarsaparilla root, and 25-100 mg. of pueraria root extract. (Fleischner '533, Column 7 line 53 to Column 8 line 37). Using a conversion factor based on the purest form of Vitamin E in terms of International Units or "IU", 25-400 IU of Vitamin E is equal to 16.75-268 mg. of Vitamin E. Accordingly, while the dietary supplement composition disclosed by Fleischner '533 that is designed for humans with Type A blood includes green tea leaf extract, it does not include either one of bush plum or grape skin extract. Thus, contrary to the antioxidant composition of claim 1 of the present application, the dietary supplement composition disclosed by Fleischner '533 does not include from 15 to 70% by weight of secondary ingredients comprising bush plum, green tea extract and grape skin extract.

Therefore, it is impossible to render the subject matter of claim 1 as a whole obvious based on Fleischner '533, and the above explicit terms of the statute cannot be met. As a result, the Examiner's burden of factually supporting a *prima facie* case of obviousness clearly cannot be met with respect to claim 1, and a rejection under 35 U.S.C. §103(a) is therefore improper.

There is still another compelling, and mutually exclusive, reason why Fleischner '533 cannot be applied to reject claim 1 under 35 U.S.C. §103(a).

The PTO also provides in MPEP §2142:

[T]he examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. ...[I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Here, Fleischner '533 does not teach, suggest or motivate the desirability of the subject matter of claim 1 since the patent does not teach, suggest or motivate an antioxidant composition that includes from 15 to 70% by weight of secondary ingredients comprising bush plum, green tea extract and grape skin extract.

Thus, Fleischner '533 does not provide any incentive or motivation supporting the desirability of the subject matter of claim 1. Therefore, there is simply no basis in the art to support a rejection of claim 1 under 35 U.S.C. §103(a) over Fleischner '533.

In view of the above, it is clear that the rejection of claim 1 under 35 U.S.C. §103(a) over Fleischner '533 should be withdrawn.

Accordingly, since Fleischner '533 does not disclose or suggest the subject matter of claim 1, it also does not disclose or suggest the subject matter of claims 5, 8 10-14, 18 and 20 which depend directly or indirectly from claim 1. Therefore, it is respectfully requested that the rejection of claims 1, 5, 8, 10-14, 18 and 20 under 35 U.S.C. § 103(a) over Fleischner '533 be withdrawn.

Claims 15-17, 19 and 21-22 stand rejected under 35 U.S.C. § 103(a) over Fleischner '533 in view of Packer et al., Direct observation of a free radical interaction between vitamin E and vitamin C, *Nature* (1979), Vol. 278, pp. 737-738 ("Packer"). Insofar as it may be applied to the present claims, this rejection is respectfully traversed.

Independent claim 15 is directed to an antioxidant composition that includes:

- quercetin;
- a mixture of alpha, beta, delta, and gamma tocopherols;
- grape skin extract;
- green tea extract; and
- bush plum.

According to claim 15, the quercetin and the mixture of tocopherols account for between 12.1% and 100% by weight of the antioxidant composition. Also according to claim 15, the quercetin and mixture of tocopherols are present in the composition in a weight ratio of from 40/60 to 90/10 percent.

Each of claims 16-17 and 21-22 depends directly or indirectly from claim 15 and therefore includes at least the foregoing elements. Claim 19 depends indirectly from claim 1 and includes the elements discussed above with respect to claim 1.

To sustain the present rejection of claims 15-17, 19 and 21-22 under 35 U.S.C. § 103(a), a *prima facie* case of obviousness must be established. MPEP § 2142 provides that a *prima facie* case of obviousness requires three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

As noted above, Fleischner '533 discloses various dietary supplement compositions that are said to be designed to be responsive to specific blood types and to be "useful in achieving and maintenance of a healthy status". (Fleischner '533, Abstract and Column 2, lines 33-40). Fleischner '533 discloses a dietary supplement composition that is alleged to be designed for humans with Type A blood which includes 50-500 mg. of Vitamin C, 25-400 IU of Vitamin E (as d-alpha-tocopheryl succinate and 50% from natural d-alpha-, d-beta-, d-gamma-, and d-delta-tocopherols), 100-400 mcg. of folate, 10-50 mcg. of Vitamin B-12, 25-200 mg. of Hawthorn berry standardized extract, 50-250 mg. of quercetin dehydrate, 50-200 mg. of milk thistle seed extract, 10-50 mg. of alfalfa leaf, 10-50 mg. of Aloe vera leaf gel 200:1 concentrate, 10-100 mg. of Burdock root, 10-50 mg. of Fenugreek seed, 10-100 mg. of ginger root, 50-200 mg. of green tea leaf extract, 25-300 mg. of St. John's Wort standardized extract, 10-50 mg. of slippery elm bark, 10-50 mg. of skull cap root, 10-50 mg. of parsley leaf, 10-100 mg. of dandelion root, 10-50 mg. of chamomile flower, 10-50 mg. of sarsaparilla root, and 25-100 mg. of pueraria root extract. (Fleischner '533, Column 7 line 53 to Column 8 line 37). Using a conversion factor based on the purest form of Vitamin E in terms of International Units or "IU", 25-400 IU of Vitamin E is equal to 16.75-268 mg. of Vitamin E.

Contrary to the antioxidant composition of claims 1 and 15 of the present application, Fleischner '533 does not disclose or suggest an antioxidant composition that includes grape skin extract and bush plum.

Packer discloses that in systems that include both Vitamins C and E, Vitamin E acts as the primary antioxidant and the resulting Vitamin E radical reacts with Vitamin C to regenerate Vitamin E. Packer, however, does not disclose or suggest an antioxidant composition that includes grape skin extract and bush plum.

Accordingly, even if a reason could be found for combining the disclosures of Fleischner '533 and Packer, the resulting combination would not disclose, motivate or suggest each and every element of claims 15-17, 19 and 21-22, since both references are totally lacking in a disclosure or suggestion of an antioxidant composition that includes grape skin extract and bush plum. Consequently, even if a combination of Fleischner '533 and Packer were possible, the resulting combination would not disclose, motivate or suggest the antioxidant composition of claims 15-17, 19 and 21-22.

According to the Office action mailed June 28, 2007, it is alleged that because Packer discloses that vitamin C regenerates vitamin E, "[i]t would have been obvious to modify Fleischner by adding a vitamin C-containing ingredient to the vitamin E-containing composition in order to gain the advantages of regeneration of vitamin E, such as ensuring effective vitamin E to the individual." (Office action, page 5). Contrary to the Office action, however, it is noted that each of the dietary supplement compositions disclosed by Fleischner '533 designed for blood types A, B and AB include 50-500 mg. of vitamin C. The dietary supplement composition disclosed by Fleischner '533 that is designed for blood Type O does not include either vitamin E or vitamin C. Therefore, it is respectfully submitted that it would not be obvious to add an additional vitamin C-containing ingredient, such as bush plum, to the dietary supplements disclosed by Fleischner '533 that include vitamin E. Instead, those of ordinary skill in the art, would understand that the vitamin C present in such dietary supplements would enable the regeneration of vitamin E. Thus, there would be no reason to add to the dietary supplements an additional vitamin C-containing ingredient such as bush plum.

In view of the foregoing, it is clear that Fleischner '533 and Packer, either alone or in combination, fail to satisfy the third requirement of a prima facie case of obviousness with respect to claims 15-17, 19 and 21-22. Failure to satisfy even one of the requirements negates the prima facie case. Accordingly, Applicants submit that the rejection of claims 15-17, 19 and

21-22 under 35 U.S.C. § 103(a) over Fleischner '533 in view of Packer is improper and request that it be withdrawn.

Conclusion

It is believed that all matters set forth in the Office action have been addressed. Favorable consideration and allowance of claims 1, 5, 8 and 10-22 are respectfully requested. Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite consideration of the claims, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



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